

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NUMBER VIS-0008-P2 SERIAL NUMBER _____ FILED _____
 FIRST INVENTOR: ELLIS, ET AL. TITLE OPHTHALMIC PREPARATION
CONTAINING GLYCOMACROPEPTIDE
 EXAMINER _____ ART UNIT _____

1. ☒ Applicant submits herewith a copy of (a) attached form PTO-1449, which lists all patents, publications, applications, or other information submitted for consideration by the Office; (b) a legible copy of each document required by 37 C.F.R. §1.98(b)(2).
2. ☒ Applicant herein apprises the Patent Office of references cited in a parent U.S. application from which this application obtains the benefit of an earlier filing date under 35 U.S.C. §120. The Serial Number of the parent application is U.S. Application PCT/US02/31657 filed OCT. 03-2002 and entitled Glycoprotein and/or Glycomacropetide The publications cited therein are listed on attached Form PTO-1449. In accordance with 37 C.F.R. §1.98(d) copies of the listed publications are not required. ☐ Additional parent patent applications are listed on an attached sheet.
3. ☐ In accordance with 37 C.F.R. §1.98(a)(3), Applicant hereby certifies that for each reference not in English (check at least one box below):
 - ☐ A copy of a translation of one or more non-English document, or portion thereof, is provided herewith;
 - ☐ A concise explanation is (check at least one box below):
 - ☐ provided in the accompanying foreign or international search report; ☐ incorporated into the specification; and/or ☐ provided herewith.

37 C.F.R. §1.97(b)(1), (b)(2) – WITHIN 3 MONTHS OF FILING OR ENTRY IN NATIONAL STAGE

4. ☒ Since this Information Disclosure Statement is being filed within three months of the filing date of the subject application or within three months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application, no fee or certification under 37 C.F.R. §1.97(e) is required.

37 C.F.R. §1.97(b)(3), (b)(4) – PRIOR TO MAILING OF FIRST OFFICE ACTION OR FIRST ACTION AFTER REQUEST FOR CONTINUED EXAMINATION

5. ☐ Since this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits, or before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114, no fee or certification under 37 C.F.R. §1.97(e) is required.

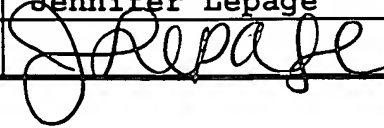
37 C.F.R. §1.97(c) – AFTER FIRST ACTION, BEFORE FINAL ACTION OR ALLOWANCE

6. ☐ Since this Information Disclosure Statement is being filed outside of the period provided for in 37 C.F.R. §1.97(b), but before the mailing date of a Final Rejection or Notice of Allowance, this submission is being accompanied by (one of the following boxes must be checked):
 - a. ☐ the fee required under 37 C.F.R. §1.97(c)(2) and specified in 37 C.F.R. §1.17(p).
 - b. ☐ the statement specified in 37 C.F.R. §1.97(e) (Box 8 or 9 must be checked).

37 C.F.R. §1.97(d) – AFTER FINAL REJECTION OR ALLOWANCE

7. ☐ Since this Information Disclosure Statement is being filed after the period specified in 37 C.F.R. §1.97(c), but on or before payment of the issue fee and is accompanied by both the statement specified in 37 C.F.R. §1.97(e) and the fee set forth in 37 C.F.R. §1.17(p). (Box 8 or 9 must be checked.)
8. ☐ In accordance with 37 C.F.R. §1.97(e)(1), Applicant's attorney certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. ☐ The foreign or international search report(s) is/are enclosed.
9. ☐ In accordance with 37 C.F.R. §1.97(e)(2), Applicant's attorney certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of the information disclosure statement.
10. ☒ In the event the Commissioner of Patents deems that any additional fee is required under 37 C.F.R. §§ 1.16 or 1.17 in connection with this application, Applicant's attorneys authorize that such fee be charged to Deposit Account No. 06-1130.
11. Consideration of this Information Disclosure Statement is respectfully requested.

Name: Daniel F. Drexler	Registration Number: 47,535
Signature: _____	Date: March 30, 2004

CERTIFICATE OF MAILING OR TRANSMISSION: I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or [<input type="checkbox"/> facsimile transmitted to the Patent and Trademark Office to Facsimile No. _____ on the date shown below.	
Name: Jennifer Lepage	Date: March 30, 2004
Signature: 	



INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>				Docket Number (Optional) VIS-0008-P2		Application Number	
				Applicant(s) EDWARD J. ELLIS, ET AL.			
				Filing Date		Group Art Unit	

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5,578,586	11/26/96	Glonek, et al.			
		5,371,108	12/06/94	Korb, et al.			
		5,294,607	03/15/94	Glonek, et al.			
		5,278,151	01/11/94	Korb, et al.			
		4,914,088	04/03/90	Glonek, et al.			
		4,818,537	04/04/89	Guo			
		4,804,539	02/14/89	Guo, et al.			
		5,460,834	10/24/95	Bhagat			
		6,180,093	01/30/01	De, et al.			
		5,075,104	12/24/91	Gressel, et al.			
		5,209,927	05/11/93	Gressel, et al.			

FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS		<i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>
		Stuart Patton, et al.; "The Epithelial Mucin, MUC1, of Milk, Mammary Gland and Other Tissue"; Biochemica et Biophysica Acta 1241 (1995) pages 407-424
		L.T. Pallesen, et al.; "Purification of MUC1 from Bovine Milk-Fat Globules and Characterization of a Corresponding Full-Length cDNA Clone"; J. Dairy Sci. 84:2591-2598; American Dairy Science Association 2001

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5,225,196	07/06/93	Robinson			
		4,983,392	01/08/91	Robinson			
		4,615,697	10/07/86	Robinson			
		5,403,841	04/04/95	Lang, et al.			
		6,056,950	05/02/00	Saettone, et al.			
		4,438,100	03/20/84	Balslev, et al.			
		6,281,192	08/28/01	Leahy, et al.			
		6,429,194	08/06/02	Leahy, et al.			
		4,615,697	10/07/86	Robinson			
		5,188,826	02/23/93	Chandrasekaran, et al.			
		2002/0045582	04/18/02	Margolin, et al.			

FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>		
		International Search Report; PCT/US02/31657; 03 March 2003

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		Filing Date	Group Art Unit

*EXAMINER INITIAL	OTHER DOCUMENTS	<i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>
		FUJIHARA et al., Lactoferrin suppresses loss of corneal epithelial integrity in a rabbit short-term dry eye model. J. Ocul Pharmacol Ther. April 1998; 14(2):99-107. Abstract. Use of lactoferrin (glycoprotein isolatable from bovine milk whey, inherently autoclavable), in a concentration of 0.01 to 1% as a suggested ophthalmic preparation for corneal epithelial integrity (i.e. dry eye treatment).
		CHU et al. Isolation and characterization of porcine milk lactoferrin. Am J Vet Res. July 1993; 54(7):1154-9 P. 1154, left column, first paragraph (lactoferrin "molecular mass is estimated to be between 72,000-85,000 daltons).
		HWANGBO, et al. Purification and characterization of novel whey glycoprotein WGP-88 which binds to a monoclonal antibody to PAS-4 glycoprotein in the bovine milk fat globule membrane. Biosci Biotechnol Biochem. September 1997; 61(9): 1568-74 P. 1571, left column, 4th paragraph, glycoproteins WGP-88 contained a 17.1% carbohydrate and PAS-4 had 7.2%. P. 1568 discusses phospholipids and glycoproteins as constituents of bovine milk (which could be isolated alone or together).
EXAMINER		DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.